

b.) Remarks

Claim 1 has been amended in order to recite the present invention with the specificity required by statute. Additionally, withdrawn claims 20, 26, 27, 41, 51 and 52 are cancelled without prejudice or disclaimer in order to reduce the issues. Dependent claims 53-58 are added in order to recite various preferred embodiments of the present invention.

The subject matter of the amendment is found in the specification as filed, *inter alia*, at page 38, lines 5-14. Accordingly, no new matter has been added.

Claims 1, 8 and 9 remain rejected under 35 U.S.C. § 103(a) as being obvious over Greenlee (WO 03/022283) in view of Shimada (WO 99/12546). According to the Examiner, the showings of record evidence unexpected superiority over the prior art, but the showing of unexpected results is at specific dosages, which are not recited in the claims. That is to say, the Examiner contends the scope of the claims is not commensurate with the evidence of unexpected results.

In order to respond to the rejection, then, Applicants have above amended all claims to recite a claimed oral dosage range of 0.001-1000 mg/kg of selective serotonin reuptake inhibitor and 0.0001-50 mg/kg of Compound I¹. As the Examiner will appreciate, it is clear from Dr. Kanda's previous Declaration (of record) as well as Test Example 2 at specification pages 33-35 that the oral administration of 0.04 mg/kg of KW-6002 and 2.5 mg/kg of paroxetine hydrochloride or 10 mg/kg fluoxetine hydrochloride shows synergistic effect for treating depression.

¹ Hereinafter, "KW-6002".

As is well-understood in this art, if the combination of two drugs which are useful for treating the same disease conclusively show a synergistic treating effect on the disease at a specific dosage of each drug, one of ordinary skill can generally expect that such combination (e.g., of the two drugs) will show the synergistic treating effect of the disease at any dosage. Accordingly, Applicants respectfully submit the results of Test Example 2 and Dr. Kanda's previous Declaration, evidence to one of ordinary skill that the synergistic treating effect would have been obtained throughout the claimed dosage range.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1, 8, 9 and 53-58 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Lawrence S. Perry/
Lawrence S. Perry
Attorney for Applicants
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

LSP\ac